510(k) SUMMARY

1.0 Submitter :

Name : Worldmed Manufacturing Sdn. Bhd.
Address : Lot 18873, Kamunting Industrial Estate,
34600 Taiping, Perak,
Malaysia.
Phone No. : 605-892 5555
Fax No . : 605-829 5590
Contact Person : Chandrasegaran (Mr)

SEP 06 2013

Date of Preparation : May 14, 2012

2.0 Name of the Device

Powder Free Natural Rubber Latex Examination Gloves

Common Name : Patient Examination Gloves

Classification Name : Patient Examination Gloves

510(K) Number : K121844

3.0 Identification of The Legally Marketed Devices That equivalency is claimed:

Primary Predicate:

MPXX™ Powder Free Natural Rubber Latex Examination Gloves
Company : Total Glove Company Sdn Bhd.
510(K) : K110250

Additional Predicate:

Powder Free Natural Rubber Latex Examination Gloves, Blue Color, Non-Sterile
Company : Wear Safe (Malaysia) Sdn. Bhd.
510(K) : K101799

4.0 Description of the Device:

The Powder Free Natural Rubber Latex Examination Gloves meets all the requirements of ASTM Specification D3578-05(2010) Standard Specification for Rubber Examination Gloves standard.

5.0 Intended Use of the Device

The Powder Free Natural Rubber Latex Examination Gloves is a single use disposable device intended for medical purposes that is worn on the hands of healthcare and similar personnel to prevent contamination between the healthcare personnel and the patient.

6.0 Summary of the Technological Characteristics of the Device:

The Powder Free Natural Rubber Latex Examination are summarized with the following technological characteristics compared to ASTM Specification D3578-05(2010) Standard Specification for Rubber Examination Gloves or equivalent standards.

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE
Dimensions	ASTM D3578-05(2010)	Meets standard requirements
Physical Properties	ASTM D3578-05(2010)	Meets standard requirements
Thickness	ASTM D3578-05(2010)	Meets standard requirements
Biocompatibility	ISO 10993-10:2002/Amd 1:2006(E) Biological evaluation of medical devices – Part 10: Tests for irritation and delayed-type hypersensitivity – Amendment 1:2006-07-15	Pass (Not a primary skin irritant)
	ISO 10993-10:2002/Amd 1:2006(E) Biological evaluation of medical devices – Part 10: Tests for irritation and delayed-type hypersensitivity – Amendment 1:2006-07-15	Pass (Not a contact sensitizer)
Watertight (1000ml)	21 CFR 800.20	Pass

7.0 Substantial Equivalent Based on Assessment of Non-Clinical Performance Data

The performance test data of non-clinical tests that support a determination of substantial equivalence is the same as mentioned immediately above.

8.0 Substantial Equivalent Based on Assessment of Clinical Performance Data

Clinical data is not needed for gloves or most devices cleared by the 510(k) process.

9.0 Substantial Equivalence Comparison

Characteristic and parameters	Medtexx Manufacturing Sdn. Bhd.	Total Glove Company Sdn. Bhd. K110250	Wear Safe (Malaysia) Sdn. Bhd. K101799	Substantial Equivalence (SE)
Product Code	80LYY	80LYY	80LYY	
Intended use	The Powder Free Natural Rubber Latex Examination Gloves is a single use disposable device intended for medical purposes that is worn on the hands of healthcare and similar personnel to prevent contamination between the healthcare personnel and the patient.	MPXX™ Powder Free Natural Rubber Examination Gloves is a single use device intended for medical purposes that is worn on the hand of healthcare and similar personnel to prevent contamination between healthcare personnel and the patient.	Powder Free Natural Rubber Latex Examination Gloves, Blue Color, Non-Sterile is a disposable device intended for medical purpose that is intended to be worn on the hand for medical purposes to provide barrier against potentially infectious materials and other contamination	SE
Width (Size Medium)	Meets ASTM D 3578-05(2010): XS – 70 ± 10 S – 80 ± 10 M – 95 ± 10 L – 111 ± 10	Meets ASTM D 3578-05	Meets ASTM D 3578-05	SE
Overall length	-Length ≥ 240mm	-Length ≥ 240mm	Meets ASTM D 3578-05	SE
Palm thickness	0.08mm	0.08mm	Meet ASTM D 3578-05	SE
Finger thickness	0.08mm	0.08mm	Meet ASTM D 3578-05	
Tensile Strength per aging min.	18.0 MPa	Meets ASTM D 3578-05: - Tensile Strength ≥ 18MPa (≥ 18MPa per Standard)	Meet ASTM D 412	
Tensile Strength after aging min	14.0 MPa		Meet ASTM D 412	
Ultimate elongation pre aging min	650%	Meets ASTM D 3578-05: - Elongation ≥ 650%	Meet ASTM D 412	
Ultimate elongation after aging	500%		Meet ASTM D 412	
Meets Biocompatibility	Yes	Yes	Yes	SE
Duration of bio-compatibility	Limited	Limited	Limited	

Skin irritation	Passes	Passes	Not a primary skin irritant	
Dermal sensitization	Passes	Passes	Not a contact skin sensitizer	
Residual powder test	Passes	Meets Applicable Definition for Powder Free; ≤ 2 mg per glove	Meets ASTM D 6124-06	
Freedom from Holes	Meets Requirements per 21CFR800.20: Gloves Free of Holes at quality level of AQL 1.5 (AQL 2.5 required per standard)	Meets Requirements per 21CFR800.20: Gloves Free of Holes at quality level of AQL 1.5 (AQL 2.5 required per standard)	Meets ASTM D 5151-06	Yes, SE
Materials	Natural Rubber Latex	Natural Rubber Latex	Natural Rubber Latex	Yes, Substantial Equivalence
Protein Content	Meets Applicable Definition for Protein Content; ≤ max 50 (ug/dm^2)	Meets Applicable Definition for Protein Content; ≤ max 50 (ug/dm^2)	Meets ASTM D 5712-05	Yes, Identical

10.0 Conclusion

Powder Free Natural Rubber Latex Examination Gloves will perform according to the gloves performance standards referenced in section 6.0 above and meets ASTM standards and FDA requirements for water leak test on pinhole AQL. Consequently, the device is substantially equivalent to currently marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 6, 2013

WorldMed Manufacturing Sdn. Bhd.
Mr. Chandrasegaran
Unite Head, Quality Assurance & Regulatory Affairs
Lot 18873, Jalan Perusahaan
3, Kamunting Industrial Estate
Kamunting Perak
MALAYSIA 34600

Re: K121844
Trade/Device Name: Powder Free Natural Rubber Latex Examination Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYY
Dated: August 6, 2013
Received: August 12, 2013

Dear Mr. Chandrasegaran:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

FOR

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2

INDICATIONS FOR USE

Applicant	:	**WORLDMED MANUFACTURING SDN. BHD.** **LOT 18873, Kamunting Industrial Estate,** **34600 Taiping, Perak,** **Malaysia.**
510(k) Number (if known)	:	K121844
Device Name	:	**POWDER FREE NATURAL RUBBER LATEX EXAMINATION GLOVES**
Indications For Use	:	

The Powder Free Natural Rubber Latex Examination Gloves is a single use disposable device intended for medical purposes that is worn on the hands of healthcare and similar personnel to prevent contamination between the healthcare personnel and the patient.

Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter___X___

Per 21 CFR 801.109

Steven T. Elliott -S

Division Sign-Off)

ivision of Anesthesiology, General Hospital

ıfection Control, Dental Devices

510(k) Number: K121844